

Application/Control Number: 09/856,105

Art Unit: ***

Page 2

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CLAIM 1 (ORIGINAL)

A method of detecting the presence of blood in a biological sample, said method comprising the steps of:

- (i) applying a biological sample to a first region of a test matrix which test matrix comprises multiple regions;
- (ii) permitting flowing of said biological sample to a second region of said test matrix wherein said sample is placed in contact with an antiglobin immunointeractive molecule for a time and under conditions sufficient for a globin-antiglobin complex to form and detecting said globin-antiglobin complex; and
- (iii) permitting flowing of said biological sample to a third region of said test matrix wherein said sample is placed in contact with a chromogen or functional equivalent thereof for a time and under conditions sufficient for said chromogen to detect haem.

globin

I II III

immobilized?
label?

no correlation

CLAIM 2 (ORIGINAL)

2. The method according to claim 1 wherein said chromogen is guaiac, tetramethyl benzidine or ortho toluidine.

CLAIM 3 (ORIGINAL)

3. The method according to claim 2 wherein said chromogen is guaiac.

Art Unit: ***

CLAIM 4 (ORIGINAL)

4. The method according to claim 1 to 3 wherein said test matrix is a chromatographic strip.

CLAIM 5 (ORIGINAL)

5. The method according to claim 4 wherein said immunointeractive molecule is an antibody.

CLAIM 6 (ORIGINAL)

6. The method according to any one of claims 1-5 wherein said biological sample is a gastrointestinal sample.

CLAIM 7 (ORIGINAL)

7. The method according to claim 6 wherein said gastrointestinal sample is a faecal sample.

CLAIM 8 (ORIGINAL)

Art Unit: ***

8. A method of detecting lower gastrointestinal bleeding said method comprising the steps of:
- (i) applying a gastrointestinal sample to a first region of a test matrix which test matrix comprises multiple regions;
 - (ii) permitting flowing of said sample to a second region of said test matrix wherein said sample is placed in contact with an antiglobin immunointeractive molecule for a time and under conditions sufficient for a globin-antiglobin complex to form and detecting said globin-antiglobin complex; and
 - (iii) permitting flowing of said sample to a third region of said test matrix wherein said sample is placed in contact with a chromogen or functional equivalent thereof for a time and under conditions sufficient for said chromogen to detect haem; ~~here~~

wherein a positive haem result and a positive globin result is indicative of lower gastrointestinal tract bleeding.

CLAIM 9 (ORIGINAL)

9. The method according to claim 8 wherein said chromogen is guaiac, tetramethyl benzidine or ortho toluidine.

CLAIM 10 (ORIGINAL)

10. The method according to claim 9 wherein said chromogen is guaiac.

CLAIM 11 (ORIGINAL)

11. The method according to claim 8 to 10 wherein said test matrix is a chromatographic strip.

Art Unit: ***

CLAIM 12 (ORIGINAL)

12. The method according to claim 11 wherein said immunointeractive molecule is an antibody.

CLAIM 13 (ORIGINAL)

13. The method according to any one of claims 8-12 wherein said gastrointestinal sample is a faecal sample.

CLAIM 14 (ORIGINAL)

14. A method of detecting upper gastrointestinal tract bleeding said method comprising the steps of:
- (i) applying a gastrointestinal sample to a first region of a test matrix which test matrix comprises multiple regions;
 - (ii) permitting flowing of said sample to a second region of said test matrix wherein said sample is placed in contact with an antiglobin immunointeractive molecule for a time and under conditions sufficient for a globin-antiglobin complex to form and detecting said globin-antiglobin complex; and
 - (iii) permitting flowing of said sample to a third region of said test matrix wherein said sample is placed in contact with a chromogen or functional equivalent thereof for a time and under conditions sufficient for said chromogen to detect haem;

wherein a positive haem result and a positive globin result is indicative of lower gastrointestinal tract bleeding.

CLAIM 15 (ORIGINAL)

fail to comply

Art Unit: ***

15. The method according to claim 14 wherein said chromogen is guaiac, tetramethyl benzidine or ortho toluidine.

CLAIM 16 (ORIGINAL)

16. The method according to claim 15 wherein said chromogen is guaiac.

CLAIM 17 (ORIGINAL)

17. The method according to claim 14 to 16 wherein said test matrix is a chromatographic strip.

CLAIM 18 (ORIGINAL)

18. The method according to claim 17 wherein said immunointeractive molecule is an antibody.

CLAIM 19 (ORIGINAL)

19. The method according to any one of claims 14-18 wherein said gastrointestinal sample is a faecal sample.

CLAIM 20 (ORIGINAL)

Art Unit: ***

20. A method of diagnosing disease conditions, the symptoms of which include bleeding, said method comprising the steps of:

- (i) applying a biological sample to a first region of a test matrix which test matrix comprises multiple regions;
- (ii) permitting flowing of said biological sample to a second region of said test matrix wherein said sample is placed in contact with an antiglobin immunointeractive molecule for a time and under conditions sufficient for a globin-antiglobin complex to form and detection said globin-antiglobin complex; and
- (iii) permitting flowing of said biological sample to a third region of said test matrix wherein said sample is placed in contact with a chromogen or functional equivalent thereof for a time and under conditions sufficient for said chromogen to detect haem.

CLAIM 21 (ORIGINAL)

21. The method according to claim 20 wherein said chromogen is guaiac, tetramethyl benzidine or ortho toluidine.

CLAIM 22 (ORIGINAL)

22. The method according to claim 21 wherein said chromogen is guaiac.

CLAIM 23 (ORIGINAL)

23. The method according to claim 20 to 22 wherein said test matrix is a chromatographic strip.

CLAIM 24 (ORIGINAL)

24. The method according to claim 23 wherein said immunointeractive molecule is an antibody.

CLAIM 25 (ORIGINAL)

25. The method according to any one of claims 20-24 wherein said disease condition is colorectal cancer and said biological sample is a gastrointestinal sample.

CLAIM 26 (ORIGINAL)

26. The method according to claim 25 wherein said gastrointestinal sample is a faecal sample

CLAIM 27-39 (CANCELLED)